

REMARKS

I. Status Summary

Claims 1-35 were filed with the application. Of these, claims 1-12 and 32-35 have been withdrawn from consideration as being directed to non-elected inventions. Claims 1-12, 18, 21, 22, and 24 have been previously cancelled. Claims 25-30 and 36 have been cancelled herein. Claims 13-17, 19, 20, 23, and 31 remain pending in the present application. Claims 13-17, 19, 20, 23, 25-31, and 36 presently stand rejected.

Claims 13 and 20 have been amended herein. Support for the amendments can be found throughout the specification as filed, including particularly page 19, lines 13-16; page 20, lines 19-24; page 25, lines 11-14; and page 25, line 30, through page 26, line 1. No new matter has been added.

Claim 36 stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being incomplete for omitting essential steps.

Claims 13-17, 20, 23, and 36 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent Publication No. 2003/0049620 to Lai et al. (hereinafter referred to as "Lai et al.") in view of the journal article to Fulton et al. (*Clinical Chemistry*, (1997) **43**(9):1749-1756; hereinafter referred to as "Fulton et al.").

Claims 19, 25-28, and 31 presently stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lai et al. in view of Fulton et al., as applied to claims 13-17, 20, and 23 in the previous rejection, and further in view of PCT Application No. WO 93/25563 to Wallace et al. (hereinafter referred to as "Wallace et al.").

Claims 13-17, and 19 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,639,611 to Wallace et al. (hereinafter referred to as "the '611 patent") in view of the journal article to Gerry et al. (*J. Molecular Biology* (1999) **292**:251-262; hereinafter referred to as "Gerry et al. ") and further in view of Fulton et al.

Claims 20, 23, 25-28, and 31 presently stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the journal article to Chen et al. (*Genome Research* (April 2000) **10**:549-557; hereinafter referred to as "Chen et al.") in view of the journal article to Dubiley et al. (*Nucleic Acids Research* (1999) **23**(18): 19; hereinafter referred to as "Dubiley et al.").

Claims 29 and 30 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Chen et al. in view of Dubiley et al. as applied to claims 20, 23, 25-28, and 31 herein above, and further in view of U.S. Patent No. 6,013,431 to Söderlund et al. (hereinafter referred to as "Söderlund et al.").

Claims 29 and 30 presently stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lai et al. in view of Fulton et al. and Wallace et al., and further in view of Söderlund et al.

Claims 20, 23, 25-31 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,287,778 to Huang et al. (hereinafter referred to as "Huang et al.") in view of Fulton et al.

## II. Response to the 35 U.S.C. § 112, Second Paragraph, Rejection

Claim 36 presently stands rejected under 35 U.S.C. §112, second paragraph, as allegedly not pointing out and distinctly claiming the subject matter which applicants regard as the invention. Particularly, the Patent Office asserts that claim 36 lacks a step to identify how the identity of the single nucleotide polymorphism can occur based on "the identity of said microbead" if the hybridization tag used is not on the allele specific primer.

Without conceding to the assertions of the Patent Office, applicants submit that claim 36 has been cancelled herein. Accordingly, applicants submit that the 35 U.S.C. §112, second paragraph, rejection of claim 36 has been rendered moot, and respectfully request that the instant rejection be withdrawn at this time.

## III. Response to the 35 U.S.C. §103(a) Rejections

### III.A. Response to the Rejection of Claims 13-17, 20, 23, and 36 Based on Lai et al. in view of Fulton et al.

The Patent Office asserts that Lai et al. teach each and every element of independent claims 13, 20, and 36, except detection by flow cytometry. The Patent Office further contends that Fulton et al. teach methods of sorting and detecting microspheres which utilize flow cytometry, and teach these methods in conjunction with nucleic acid hybridization methodologies. The Patent Office asserts that it would have been *prima facie*

obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods taught by Lai et al. so as to have included a flow cytometry step for the detection of hybridization of the extension product, as taught by Fulton et al.

After careful review of the instant rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that in order to establish a *prima facie* case of obviousness, each and every claim limitation must be taught or suggested by the prior art references when combined. In re Royka 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicants submit that independent claim 13 has been amended herein to recite in step (c), extending hybridized primers by primer extension to produce extension products wherein said extension products comprise said hybridization tag and a hybridization tag complement. Applicants further submit that independent claim 13 has been amended herein to recite in step (d), "hybridizing said extension products by said hybridization tag or the hybridization tag complement under stringent conditions to a combination of capture probes complementary to both the hybridization tag and the hybridization tag complement, wherein said capture probes are coupled to a microbead, said microbead identifying said capture probes". Support for the amendments to claim 13 can be found throughout the specification as filed, including particularly on page 19, lines 13-16. No new matter has been added.

The Patent Office asserts that Lai et al. teach at paragraphs [0181], [0182] the step of hybridizing extension products by the hybridization tag or the complement thereof. However, applicants respectfully submit that Lai et al. appears to teach a method of hybridizing extension products by the hybridization tag complement only. Specifically, paragraphs [0181] - [0182], and Figures 3-5, 7-9 of Lai et al. appear to teach a method whereby a first primer containing a target non-complementary region (*i.e.*, a "hybridization tag") is extended to produce a first primer extension product. A second primer then hybridizes to the first primer extension product, and is extended to produce a capture sequence on the second primer extension product that is complementary to the hybridization tag on the first primer. The second primer extension product is then hybridized by the complement of the hybridization tag contained in the first primer to a

capture probe (see, Figure 9). Therefore, applicants respectfully submit that Lai et al. do not teach or suggest hybridizing extension products by both a hybridization tag and the hybridization tag complement to a combination of capture probes complementary to both the hybridization tag and the complement thereof, as presently recited in independent claim 13.

With regard to independent claim 20, applicants submit that independent claim 20 recites in step (d), *inter alia*, “hybridizing said extension product by said hybridization tag under stringent conditions to a capture probe...”. As recited hereinabove, applicants submit that Lai et al. at best teach a method of hybridizing extension products by the hybridization tag complement only, not by the hybridization tag. Thus, applicants respectfully submit that Lai et al. does not teach the step of hybridizing an extension product by the hybridization tag or hybridization tag complement as asserted by the Patent Office.

With regard to independent claim 36, applicants respectfully submit that step (a) recites, *inter alia*, providing at least one primer pair wherein both the forward and reverse primers comprise a hybridization tag. Applicants submit that, as recited hereinabove, Lai et al. teach a method utilizing a first primer containing a target non-complementary region (a hybridization tag) and a second primer lacking a hybridization tag. Thus, applicants respectfully submit that Lai et al. does not teach the step of providing a primer pair wherein both primers comprise a hybridization tag, as recited in independent claim 36.

Applicants respectfully submit that Fulton et al. does not make up for the deficiencies in Lai et al. Particularly, applicants respectfully submit that Fulton et al. does not teach a method for detecting a single nucleotide polymorphism comprising, *inter alia*, hybridizing extension products to a capture probe. Rather, Fulton et al. appears to only disclose a method wherein microspheres are spectrally encoded through differential dyeing of identically sized microspheres with two different dyes. Accordingly, applicants respectfully submit that Fulton et al. appears to be limited to disclosing various flow cytometry applications, rather than teaching methods of hybridizing an extension product to a capture probe.

Thus, the combination of Lai et al. in view of Fulton et al. does not support the instant rejection of independent claims 13, 20, and 36. Claims 14-17 and 23 ultimately depend from independent claims 13 and 20. As such, the combination of Lai et al. in view of Fulton et al. does not support the rejection of claims 14-17 and 23. Hence, applicants contend that a *prima facie* case of obviousness has not been established, and respectfully request that the instant rejection of claims 13-17, 20, 23, and 36 under 35 U.S.C. §103(a) be withdrawn at this time. Allowance of claims 13-17, 20, and 23 is also respectfully requested.

III.B. Response to the Rejection of Claims 19, 25-28, and 31 Based on  
Lai et al. in view of Fulton et al. and Further in view of Wallace et al.

Claims 19, 25-28, and 31 presently stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lai et al. in view of Fulton et al., as applied to claims 13-17, 20, and 23 in the previous rejection, and further in view of Wallace et al.

The Patent Office concedes that Lai et al. in view of Fulton et al. does not teach the application of the disclosed methodology for diagnosing a disease, condition, disorder, or predisposition. The Patent Office further concedes that Lai et al. in view of Fulton et al. does not teach methods wherein primer extension is single base primer extension. However, the Patent Office asserts that Wallace et al. makes up for the deficiencies of Lai et al. in view of Fulton et al.

Initially, without conceding to the assertions of the Patent Office, claims 25-28 have been cancelled herein. As such, the rejection of these claims is believed to have been rendered moot.

As discussed hereinabove, applicants respectfully submit that the cited combination of Lai et al. in view of Fulton et al. does not support the instant rejection of independent claims 13 or 20. As such, applicants respectfully submit that the cited combination of Lai et al. in view of Fulton et al. also does not support the instant rejection of claims 19 and 31, which depend from independent claims 13 and 20. Applicants further submit that Wallace et al. does not make up for the deficiencies of Lai et al. in view of Fulton et al.

With particular regard to independent claim 13, applicants respectfully submit that

Wallace et al. does not teach a method for detecting a single nucleotide polymorphism comprising, *inter alia*, hybridizing said extension products by said hybridization tag or the hybridization tag complement under stringent conditions to a combination of capture probes complementary to both the hybridization tag and the hybridization tag complement. Rather, at best, Wallace et al. appears to be limited to methods of detecting an allele through the hybridization of a hybridization tag to a sequence within a solid support.

With particular regard to independent claim 20, applicants further respectfully submit that Wallace et al. does not make up for the deficiencies of Lai et al. in view of Fulton et al.

Specifically, applicants respectfully submit that Wallace et al. does not teach hybridizing extension products by hybridization tag to a capture probe, wherein the capture probe is coupled to a microbead that identifies said capture probe, as recited in independent claim 20, step (d). Rather, the Patent Office is relying on the assertion that Wallace et al. teach single base primer extension (see, Official Action, page 8).

Therefore, applicants submit that a *prima facie* case of obviousness has not been established with regard to independent claims 13 and 20 over Lai et al. in view of Fulton et al., and further in view of Wallace et al. Accordingly, applicants submit that a *prima facie* case of obviousness has not been established as to claims 19 and 31, which depend from independent claims 13 and 20. Thus, applicants respectfully request that the instant rejection of claims 19 and 31 under 35 U.S.C. §103(a) be withdrawn at this time. Allowance of claims 19 and 31 is also respectfully requested.

III.C. Response to the Rejection of Claims 13-17 and 19 Based on the '611 Patent in view of Gerry et al. and Further in view of Fulton et al.

Claims 13-17 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the '611 Patent in view of Gerry et al. and further in view of Fulton et al.

The Patent Office contends that the '611 Patent teaches a method for detecting single nucleotide polymorphisms comprising steps (a)-(c) of the instant application, and the capture of PCR products using a biotin-streptavidin interaction for the detection of a particular allele. The Patent Office concedes that the '611 Patent does not teach a method wherein the forward primer comprises a hybridization tag that identifies the primer, said

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hybridization tag not complementary to the sequence containing the single nucleotide polymorphism of interest. The Patent Office further concedes that the '611 Patent does not teach hybridizing extension products via the tag to a probe coupled to a particle, detecting the hybridization and identifying the single nucleotide polymorphism based upon the identity of said particle. Further, the Patent Office concedes that '611 Patent does not teach a method wherein at least one primer pair comprises a plurality of primer pairs specific for a plurality of single nucleotide polymorphisms.

The Patent Office asserts that Gerry et al. address the deficiencies of '611 Patent and that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods taught by the '611 Patent so as to have used the binary primer taught by Gerry et al. The Patent Office concedes that the '611 Patent in view of Gerry et al. does not teach a method wherein the capture probes are attached to microbeads and wherein the detection occurs by flow cytometry. However, the Patent Office argues that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods taught by the '611 Patent in view of Gerry et al. so as to have provided a microsphere-based assay that included a flow cytometry step for the detection of hybridization of the extension product, as taught by Fulton et al.

After careful review of the instant rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that, as discussed herein above, independent claim 13 has been amended to recite, *inter alia*, in step (c), extending hybridized primers by primer extension to produce extension products wherein said extension products comprise said hybridization tag and a hybridization tag complement. Applicants further submit that independent claim 13 has been amended herein to recite in step (d), "hybridizing said extension products by said hybridization tag or the hybridization tag complement under stringent conditions to a combination of capture probes complementary to both the hybridization tag and the hybridization tag complement...". Applicants respectfully submit that none of the cited references, either alone or in combination teach claim 13, as currently amended.

The Patent Office relies on Gerry et al. to allegedly teach hybridization of primers to a capture probe. Applicants respectfully submit that Gerry et al. further do not teach hybridizing said extension products by said hybridization tag or the hybridization tag complement under stringent conditions to a combination of capture probes complementary to both the hybridization tag and the hybridization tag complement. Rather, Gerry et al. teach that reacted primers are hybridized to a capture probe that binds the hybridization tag. Gerry et al. do not teach binding the reacted primers to a combination of capture probes that are complementary to both the hybridization tag and the hybridization tag complement.

Applicants respectfully submit that the '611 patent does not make up for the deficiencies of Gerry et al. Particularly, applicants respectfully submit that the '611 patent teaches a method of ASPCR, and does not recite the step of hybridizing to a capture probe. Rather, the '611 patent teaches methods of analyzing PCR reaction products by gel electrophoresis.

Applicants further respectfully submit that Fulton et al. does not make up for the deficiencies in Gerry et al. and the '611 Patent, either alone or in combination. Particularly, applicants respectfully submit that Fulton et al. does not teach a method for detecting a single nucleotide polymorphism comprising, *inter alia*, hybridizing extension products to a capture probe. Rather, Fulton et al. at best disclose a method wherein microspheres are spectrally encoded through differential dyeing of identically sized microspheres with two different dyes. Accordingly, applicants respectfully submit that Fulton et al. appears to be limited to disclosing various flow cytometry applications, rather than teaching a method of hybridizing extension products to a capture probe.

Therefore, it is believed that a *prima facie* case of obviousness has not been established as to independent claim 13. Applicants further submit that a *prima facie* case of obviousness therefore has not been established as to claims 14-17 and 19, which depend from independent claim 13. Applicants respectfully request that the instant rejection of claims 13-17 and 19 under 35 U.S.C. §103(a) be withdrawn at this time. Allowance of claims 13-17 and 19 is also respectfully requested.



III.D. Response to the Rejection of Claims 20, 23, 25-28, and 31 Based on  
Chen et al. in view of Dubiley et al.

Claims 20, 23, 25-28, and 31 presently stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chen et al. in view of Dubiley et al.

The Patent Office contends that Chen et al. teach each step of independent claim 20. However, the Patent Office concedes that Chen et al. do not teach a method wherein at least one primer comprises a group of at least 2 primers, each primer in said group having a 3' end specific for a different allele of a single nucleotide polymorphism of interest.

The Patent Office asserts that Dubiley et al. meets the deficiencies of Chen et al. and teach a single nucleotide extension method for the detection of polymorphic alleles which utilize primers that contain different 3'-terminal nucleotide overlapping the variable DNA, and teach a group of at least 2 primers having a 3' end specific for different alleles of a single nucleotide polymorphism of interest.

The Patent Office further asserts that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have utilized the primers taught by Dubiley et al. in the methods taught by Chen et al. so as to have provided a method which utilizes a pair of at least 2 primers, each primer in said group having a 3' end specific for a different allele of a single nucleotide polymorphism of interest.

After careful review of the rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

While not conceding to the Patent Office's assertions, applicants respectfully submit that claims 25-28 have been cancelled herein. Accordingly, it is believed that the rejection of these claims has been rendered moot.

Further, applicants respectfully submit that claim 20 has been amended herein to recite, in step (c), extending hybridized primers by multi-base primer extension to produce an extension product, said extension product comprising said hybridization tag and a detectable label. Support for the amendment to claim 20 can be found throughout the application as filed, including particularly at page 25, lines 9-17; and page 26, line 27, through page 27, line 3. No new matter has been added. Applicants submit that the cited combination of Chen et al. in view of Dubiley et al. teach does not teach this element.

In particular, applicants submit that Chen et al. does not teach a method of detecting single base polymorphisms comprising the step of extending hybridized primers by multi-base primer extension. Rather, Chen et al. appears to be limited to methods of single base chain extension. See, for example, title, abstract, Figure 1.

Applicants respectfully submit that the deficiencies of Chen et al. are not cured by the teachings of Dubiley et al. Particularly, applicants submit that Dubiley et al. do not teach a method of detecting single base polymorphisms comprising the step of extending hybridized primers by multi-base primer extension. Rather, Dubiley et al. teach using fluorescently labeled ddNTPs to identify a base in a polymorphic site with one primer. See, for example, page 1, column 2, paragraph 2. Accordingly, Dubiley et al. also appears to be limited to methods of single base chain extension.

Thus, applicants respectfully submit that the cited combination of Chen et al. in view of Dubiley et al. do not teach each and every element of independent claim 20. Applicants further submit that the cited combination also does not teach each and every element of dependent claims 23 and 31, which depend from independent claim 20.

Therefore, applicants respectfully submit that a *prima facie* case of obviousness has not been established, and respectfully request that the instant rejection of claims 20, 23, and 31 under 35 U.S.C. §103(a) be withdrawn at this time. Allowance of claims 20, 23, and 31 is also respectfully requested.

III.E. Response to the Rejection of Claims 29 and 30 Based on Chen et al. in view of Dubiley et al. and further in view of Söderlund et al.

Claims 29 and 30 presently stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chen et al. in view of Dubiley et al. as applied to claims 20, 23, 25-28, and 31 and further in view of Söderlund et al.

The Patent Office asserts that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method taught by Chen et al. so as to have included differentially labeled ddNTPs as taught by Söderlund et al. within the reaction mixture in order to detect more than one point mutation occurring at the same site of an undivided sample.

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Without conceding to the Patent Office's assertions, claims 29 and 30 have been cancelled herein. As such, it is believed that the instant rejection of claims 29 and 30 has been rendered moot. Accordingly, applicants respectfully request that the instant rejection of claims 29 and 30 under 35 U.S.C. §103(a) be withdrawn at this time.

III.F. Response to the Rejection of Claims 29 and 30 Based on Lai *et al.* in view of Fulton *et al.* and Wallace *et al.* and Further in view of Söderlund *et al.*

Claims 29 and 30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lai *et al.* in view of Fulton *et al.* and Wallace *et al.*, and further in view of Söderlund *et al.*

The Patent Office asserts that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method taught by Lai *et al.* in view of Fulton *et al.* and Wallace *et al.* so as to have included differentially labeled ddNTPs as taught by Söderlund *et al.* within the reaction mixture in order to detect more than one point mutation occurring at the same site of an undivided sample.

Without conceding to the Patent Office's assertions, claims 29 and 30 have been cancelled herein. As such, it is believed that the instant rejection of claims 29 and 30 has been rendered moot. Accordingly, applicants respectfully request that the instant rejection of claims 29 and 30 under 35 U.S.C. §103(a) be withdrawn at this time.

III.G. Response to the Rejection of Claims 20, 23, and 25-31 Based on Huang *et al.* in view of Fulton *et al.*

Claims 20, 23, and 25-31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Huang *et al.* in view of Fulton *et al.*

The Patent Office contends that Huang *et al.* teach a method comprising each step of independent claim 20 except detection by flow cytometry.

The Patent Office asserts that Fulton *et al.* teach methods of sorting and detecting microspheres which utilize flow cytometry, and in particular teach these methods in conjunction with nucleic acid hybridization methodologies.

The Patent Office argues that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods taught by Huang et al. so as to have included a flow cytometry step for the detection of hybridization of the extension product, as taught by Fulton et al. The Patent Office asserts that one would have been motivated to use flow cytometry to detect the microspheres taught by Huang et al. in order to take advantage of such a system as taught by Fulton et al.

After careful review of the instant rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejections and submit the following remarks.

Without conceding to the assertions of the Patent Office, applicants respectfully submit that claims 25-30 have been cancelled herein. Accordingly, it is believed that the rejection of these claims has been rendered moot.

Initially, applicants respectfully submit that independent claim 20 has been amended herein to recite, *inter alia*, in step (d), hybridizing said extension product by said hybridization tag under stringent conditions to a capture probe, wherein said capture probe is coupled to a fluorescent microbead that identifies said capture probe. Support for the amendment to claim 20 can be found throughout the application as filed, including particularly at page 20, lines 19-24, and page 25, line 30, though page 26, line 1. Applicants respectfully submit that the cited combination of Huang et al. in view of Fulton et al. do not recite this element.

Particularly, applicants respectfully submit that Huang et al. do not teach a method of detecting a single nucleotide polymorphism comprising the step of hybridizing extension products a hybridization tag to a capture probe, wherein the capture probe is coupled to a fluorescent microbead that identifies the capture probe. Rather, applicants submit that Huang et al. teach that labeled extension product can be hybridized to one or more probes immobilized to known locations on a wide variety of non-fluorescent supports (see, for example, column 5, lines 43-47).

Applicants respectfully submit that Fulton et al. does not make up for the deficiencies of Huang et al. Particularly, Fulton et al. do not teach or suggest a method of detecting a single nucleotide polymorphism comprising the step of hybridizing an extension

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product by a hybridization tag under stringent conditions to a capture probe, wherein the capture probe is coupled to a fluorescent microbead that identifies said capture probe. Rather, at best, Fulton et al. discloses various applications of flow cytometry.

Thus, applicants respectfully submit that the cited combination of Huang et al. in view of Fulton et al. do not teach each and every element of independent claim 20. Accordingly, applicants submit that the cited combination also does not teach each and every element of claims 23 and 31, which depend from independent claim 20.

Therefore, applicants respectfully submit that a *prima facie* case of obviousness has not been established, and that the instant rejection of claims 20, 23, and 31 under 35 U.S.C. §103(a) be withdrawn at this time. Allowance of claims 20, 23, and 31 is also respectfully requested.

#### CONCLUSIONS

In light of the above Remarks, it is respectfully submitted that the present application is now in a proper condition for allowance and such action is earnestly solicited. If any minor issues should remain outstanding after the Patent Examiner has had an opportunity to study the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney so that all such matters may be resolved and the application be placed in a condition for allowance without the necessity for issuance of another Official Action.

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DEPOSIT ACCOUNT

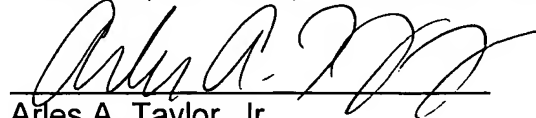
The Commissioner is hereby authorized to charge any deficiencies of payment or credit any overpayments associated with the filing of this Amendment to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

Date: May 19, 2006

By:



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